(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 864.3.

[45 FR 60642, Sept. 12, 1980, as amended at 52 FR 17733, May 11, 1987]

§ 864.9225 Cell-freezing apparatus and reagents for in vitro diagnostic use.

(a) *Identification.* Cell-freezing apparatus and reagents for in vitro diagnostic use are devices used to freeze human red blood cells for in vitro diagnostic use.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60643, Sept. 12, 1980, as amended at 65 FR 2310, Jan. 14, 2000]

§ 864.9245 Automated blood cell separator.

(a) *Identification.* An automated blood cell separator is a device that automatically removes whole blood from a donor, separates the blood into components (red blood cells, white blood cells, plasma, and platelets), retains one or more of the components, and returns the remainder of the blood to the donor. The components obtained are transfused or used to prepare blood products for administration. These devices operate on either a centrifugal separation principle or a filtration principle. The separation bowls of centrifugal blood cell separators may be reusable or disposable.

(b) *Classification of device operating by filtration separation principle.* Class II (special controls). The special controls for the device are that the manufacturer must file an annual report with FDA for 3 consecutive years. Each annual report must include the following:

(1) A summary of adverse donor reactions reported by the users to the manufacturer that do not meet the threshold for medical device reporting under part 803 of this chapter;

(2) Any change to the device, including but not limited to:

(i) New indications for use of the device;

(ii) Labeling changes, including operation manual changes;

(iii) Computer software changes, hardware changes, and disposable item changes, e.g., collection bags, tubing, filters;

(3) Equipment failures, including software, hardware, and disposable item failures, e.g., collection bags, tubing, filters.

(c) *Classification of device operating by centrifugal separation principle.* Class III (premarket approval).

(d) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (c) of this section. See § 864.3.

[45 FR 60645, Sept. 12, 1980, as amended at 52 FR 17733, May 11, 1987; 68 FR 9532, Feb. 28, 2003]

§ 864.9275 Blood bank centrifuge for in vitro diagnostic use.

(a) *Identification.* A blood bank centrifuge for in vitro diagnostic use is a device used only to separate blood cells for further diagnostic testing.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60645, Sept. 12, 1980, as amended at 65 FR 2310, Jan. 14, 2000]

§ 864.9285 Automated cell-washing centrifuge for immuno-hematology.

(a) *Identification.* An automated cell-washing centrifuge for immuno-hematology is a device used to separate and prepare cells and sera for further in vitro diagnostic testing.

(b) *Classification.* Class II (performance standards).

[45 FR 60646, Sept. 12, 1980]

§ 864.9300 Automated Coombs test systems.

(a) *Identification.* An automated Coombs test system is a device used to detect and identify antibodies in patient sera or antibodies bound to red cells. The Coombs test is used for the diagnosis of hemolytic disease of the newborn, and autoimmune hemolytic anemia. The test is also used in crossmatching and in investigating